FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
Endocrinologic and Metabolic Drugs Advisory Committee
Hilton Hotel, Washington North/Gaithersburg, Maryland
620 Perry Pkwy, Gaithersburg, Maryland
July 15, 2010
Qnexa

Questions to the Advisory Committee

1) Taking into account the results of the assessments made with the PHQ-9 and the Columbia Suicidality Severity Rating Scale (C-SSRS), please comment on the significance of the increased adverse event reports of depression, anxiety, and sleep disorders in subjects treated with Phentermine/Topiramate (PHEN/TPM).

    - If approved, please discuss need for monitoring, possible monitoring strategies, and contraindications for use.

2) Please comment on the potential significance of the increased adverse event reports of disorders of attention, memory, language, and other cognitive disorders in subjects treated with PHEN/TPM.

    - If approved, please discuss need for monitoring and possible monitoring strategies.

3) Please comment on the potential clinical significance of the metabolic acidosis determined by decreases in serum bicarbonate levels with PHEN/TPM treatment.

    - If approved, please discuss need for monitoring, possible monitoring strategies, and contraindications for use.

4) Please comment on the potential clinical significance of the increase in heart rate observed in PHEN/TPM treated individuals.

    - If approved, please discuss need for monitoring, possible monitoring strategies, and contraindications for use.

5) Given the doses of topiramate in PHEN/TPM, please comment on whether you believe PHEN/TPM poses a teratogenic risk to the target population for weight loss.

    - If you believe it does pose a risk, please comment on how this risk should be managed in women of child-bearing potential if PHEN/TPM is approved.

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6) Based on the current available data, do you believe the overall benefit-risk assessment of PHEN/TPM (QNEXA) is favorable to support its approval for the treatment of obesity in individuals with a BMI ≥30 kg/m2 or ≥27 kg/m2 with weight-related co-morbidities?

Vote: Yes/No/Abstain

If voting yes:

- Please discuss the basis for this recommendation
- Please discuss any labeling recommendations
- Please discuss whether additional studies should be conducted post-approval

If voting no:

- Please discuss basis for this recommendation
- Please discuss what additional studies would be necessary to address an outstanding deficiency/deficiencies